



MISSISSIPPI STATE DEPARTMENT OF HEALTH

**This is an official
MS Health Alert Network (HAN) Advisory**

MESSAGE ID: MSHAN-20150116-00108-ADV (Health Advisory)
RECIPIENTS: All Physicians, Hospitals, and Health care Providers - Statewide
DATE: January 16, 2015

SUBJECT: *Wallcur Practi-0.9% non-sterile, intravenous solution for simulation purposes mistakenly distributed to medical clinics*

Dear Colleagues:

The US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are investigating the inadvertent use of Wallcur's Practi-0.9% simulated intravenous (IV) saline products. This product is intended for training purposes only but was mistakenly shipped to medical clinics and urgent care facilities. This product is not sterile and is unsafe for human administration. More than 40 patients in the US have received this non-sterile product with numerous reports of adverse events and one associated death.

The Mississippi State Department of Health has been notified of a small shipment of Wallcur's Practi-0.9% distributed to a Mississippi outpatient clinic. Fortunately no product was administered to patients and the supply has been quarantined.

Clinicians and office staff are encouraged to take the following steps to ensure IV solution simulation products are removed from office inventory to eliminate the possible injection of Wallcur simulated products into patients.

- Visually inspect all current IV saline solution bags. Ensure none of the bags are labeled "Wallcur," "Practi-products," "For clinical simulation," or "Not for use in human or animal patients."
- If you have products labeled with any of these words, or you suspect you may have received other products intended for training purposes, separate simulation products from existing inventory and notify the Mississippi State Department of Health Office of Epidemiology at 601 576-7725 (or 601 576-7400 after hours).
- Consider reviewing your office procedures and make sure there are procedures in place to visually inspect all future shipments of normal saline products to ensure they are for clinical use.
- If you suspect that any Wallcur training IV products may have been administered to a patient, whether or not the incident has resulted in an adverse event, notify the Mississippi State Department of Health Office of Epidemiology at 601 576-7725 (or 601 576-7400 after hours) and pursue appropriate medical follow-up.

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Equal Opportunity in Employment/Services

No additional shipments are known to have arrived in Mississippi and outpatient settings have been identified as the destination of these products, but additional investigation by FDA and CDC is ongoing. Further information may be obtained on the FDA website at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm430360.htm>

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Alerting Message Specification Settings

Originating Agency:	Mississippi State Department of Health
Alerting Program:	MS Health Alert Network (MS HAN)
Message Identifier:	MSHAN-2015011600108-ADV
Program (HAN) Type:	Health Advisory
Status (Type):	Actual ()
Message Type:	Alert
Reference:	MSHAN-00108
Severity:	Unknown
Acknowledgement:	No
Sensitive:	Not Sensitive
Message Expiration:	Undetermined
Urgency:	Undetermined
Delivery Time:	600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency:	A unique identifier for the agency originating the alert.
Alerting Program:	The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.
Message Identifier:	A unique alert identifier that is generated upon alert activation (MSHAN-yyymmdd-hhmm-TTT (ALT=Health Alert , ADV=Health Advisory , UPD=Health Update , MSG/INFO=Message/Info Service)).
Program (HAN) Type:	Categories of Health Alert Messages.
Health Alert:	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory:	Provides important information for a specific incident or situation; may not require immediate action.
Health Update:	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Health Info Service:	Provides Message / Notification of general public health information; unlikely to require immediate action.
Status (Type):	
Actual:	Communication or alert refers to a live event
Exercise:	Designated recipients must respond to the communication or alert
Test:	Communication or alert is related to a technical, system test and should be disregarded
Message Type:	
Alert:	Indicates an original Alert
Update:	Indicates prior alert has been Updated and/or superseded
Cancel:	Indicates prior alert has been cancelled
Error:	Indicates prior alert has been retracted

Reference: For a communication or alert with a Message Type of “Update” or “Cancel”, this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. “n/a” = Not Applicable.

Severity:

Extreme:	Extraordinary threat to life or property
Severe:	Significant threat to life or property
Moderate:	Possible threat to life or property
Minor:	Minimal threat to life or property
Unknown:	Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive:	Indicates the alert contains sensitive content
Not Sensitive:	Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440, 4320 minutes (.25, 1, 24, 72 hours)).